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EXAMINER	
ROMEO, DAVID S	
ART UNIT	PAPER NUMBER
1647	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/654,994	FERGUSON, MARK W.J.	
	Examiner	Art Unit	
	David S. Romeo	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20,23,25-27 and 31-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20, 23, 25¬–27 and 31–35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed 05/28/2008 has been entered. Claims 20, 23, 25–27 and 31–35 are pending.

Maintained formal matters, objections, and/or rejections:

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22 is directed to or encompasses "a partially modified form of activin having a longer half-life than its parent molecule." The specification provides the following, regarding partial modifications:

> Partial modification may for example be by way of addition, deletion or substitution of amino acid residues. A substitution may for example be a conserved substitution. Partially modified molecules may, for example, have a longer half-life than their parent molecule … . Paragraph bridging pages 2-3.

Because the specification does not identify that material element or combination of elements which is unique to, and, therefore, definitive of "a partially modified form of activin having a longer half-life than its parent molecule" an artisan cannot determine what additional or material limitations are placed upon a claim by the presence of this element. The metes and bounds are not clearly set forth.

Applicant request withdrawal of the rejection in view of the revision of this claim. The examiner declines to withdraw the rejection because the revision does not address the metes and bounds of "a partially modified form of activin having a longer half-life than its parent molecule."

New Formal Matters, Objections and/or Rejections

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

Claim 23 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. A partially modified form of Activin (claim 23) can be infringed without infringing Activin (claim 20).

Claim 35 is objected to because of the following informalities: "wound" is misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20, 23, 25–27 and 31–35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled

in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The limitations "up to about 5 ng of Activin per centimeter of said wound or fibrotic disorder" or "2.5 ng to up to about 5 ng of Activin per centimeter of said wound or fibrotic disorder" are not supported by the disclosure as originally filed and their introduction raises the issue of new matter.

Applicant argues that:

> Support for the revision of claim 20 to recite doses of activin up to 5ng per centimeter of wound or fibrotic disorder to improve the macroscopic appearance of wounds can be found in the experimental results reported in the specification (see, for example, the final paragraph of page 14). These results also indicate that the ability to reduce macroscopic scarring decreases when the amount of activin administered is increased. The recitation of the administration of doses per centimeter of wound or fibrosis finds support in the study set out in the experimental results which makes it clear that the recited doses of activin were each administered to a 1 cm wound (see, for example, page 11, second paragraph under "Materials and Methods"). It would be clear to an artisan that these doses should be "scaled up" when treating longer wounds. Hence, one skilled in the art would recognize that it is the administration of the specified amount of activin per centimeter length of the wound that is important in achieving the biological effect required (i.e., a reduction in scarring).

Applicant's arguments have been fully considered but they are not persuasive. The wounds treated in Experiment 2 were linear incisions (page 11, paragraph 4). All injections were intradermal, approximately 50 µl delivered down each side of the incision as close as possible to the wound without rupturing it, and were administered once daily for three days, starting immediately prior to wounding (Day 0) (page 11, last paragraph). Experiment 2 only treats a single length of linear incision. Experiment 2 does not vary the length of the incision or vary the dose of Activin based on varied lengths of the incision. Therefore, Experiment 2 does not provide evidence that the specification, as filed, envisioned the concept of basing the dose of

activin administered by any route on the centimeter length of a linear incision. Therefore, the specification does not disclose the concept of scaling up the dose of activin based on the linear length of linear wounds.

As noted, all the wounds treated in Experiment 2 were linear incisions and all injections were intradermal. However, only claim 34 limits the claimed method to intradermal injection. It is fair to say that the amount of activin administered will vary depending upon the particular mode of administration and the severity of the particular condition undergoing treatment. See, for example, De Krester (U. S. Patent No. 5,196,192), column 7, lines 40-53. However, the specification does not support the concept of administering this dose of activin by any route other than local, intradermal injection.

Furthermore, the wounds and fibrotic disorders being treated in the claimed method are not limited to linear incisions. See, for example, the following passages from the specification:

> By "wounds or fibrotic disorders" is meant any condition which may result, in the formation of scar tissue. In particular, this includes the healing of skin wounds, the repair of tendon damage, the healing of crush injuries, the healing of eye wounds, including wounds to the cornea, the healing of central nervous system (CNS) injuries, conditions which result in the formation of scar tissue in the CNS, scar tissue formation resulting from strokes, and tissue adhesion, for example, as a result of injury or surgery (this may apply to e.g. tendon healing and abdominal strictures and adhesions). Examples of fibrotic disorders include pulmonary fibrosis, glomerulonephritis, cirrhosis of the liver, systemic sclerosis, scleroderma, proliferative vitreoretinopathy, repair following myocardial infarction, including myocardial hibernation. Specification at page 1, full paragraph 2.
>
> There is also a lack of compositions for use in the treatment of chronic wounds, for example venous ulcers, diabetic ulcers and bed sores (decubitus ulcers), especially in the elderly and wheel chair bound patients. Specification at page 2, full paragraph 1.
>
> …systemic therapy for e.g. fibrosis or severe trauma or burns, for example by intraperitoneal, intravenous or oral administration; eye drops for corneal wounds

> or scarring; films and barriers for treating adhesions. Specification at page 7, full paragraph 1.
>
> The method may be for use in conjunction with a composition for promoting the healing of chronic wounds. Specification at page 8, full paragraph 3.

Therefore, the claimed method encompasses the treatment of non-linear wounds and fibrotic disorders. However, the specification does not disclose the concept of scaling up the dose of Activin based on the linear length of non-linear wounds.

For these reasons the limitations introduce new concepts, change the meaning, scope and content of the disclosure, and violate the description requirement of 35 U.S.C. § 112, first paragraph.

Although it might be obvious to the skilled artisan that it would be desirable to scale up the dose, the written description "does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed. It extends only to that which is disclosed." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). "One shows that one is 'in possession' of the invention by describing the invention, with all its claimed limitations, not that which makes it obvious." Lockwood, id., citing Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). Applicant's arguments are therefore not persuasive.

The examiner also disagrees with applicant's characterization of the results as showing "that the ability to reduce macroscopic scarring decreases when the amount of activin administered is increased" because "...an obvious effect may have been negated by the quality of the control wounds which were on the same animal and therefore perhaps improved by systemic

effects of the high dose of Activin A" (paragraph bridging pages 14-15; see also page 14, last full paragraph).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20, 23, 25–27 and 31–35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite "up to about 5 ng of Activin per centimeter of said wound or fibrotic disorder" or "2.5 ng to up to about 5 ng of Activin per centimeter of said wound or fibrotic disorder." The wounds and fibrotic disorders being treated in the claimed method are not limited to linear incisions and encompass the treatment of non-linear wounds and fibrotic disorders, as discussed above. It is unclear how one is to determine the centimeter length of non-linear wounds and fibrotic disorders. Thus, the amount of activin to be administered is unclear. The metes and bounds are not clearly set forth.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-

filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 09/043,110, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The limitations "up to about 5 ng of Activin per centimeter of said wound or fibrotic disorder" or "2.5 ng to up to about 5 ng of Activin per centimeter of said wound or fibrotic disorder" are not supported by the disclosure as originally filed and their introduction raises the issue of new matter, as discussed above.

Oath/Declaration

This application presents a claim for subject matter not originally claimed or embraced in the statement of the invention. The limitations "up to about 5 ng of Activin per centimeter of said wound or fibrotic disorder" or "2.5 ng to up to about 5 ng of Activin per centimeter of said wound or fibrotic disorder" are not supported by the disclosure as originally filed and their introduction raises the issue of new matter, as discussed above. A supplemental oath or declaration is required under 37 CFR 1.67. The new oath or declaration must properly identify the application of which it is to form a part, preferably by application number and filing date in the body of the oath or declaration. See MPEP §§ 602.01 and 602.02.

The surcharge set forth in 37 CFR 1.16 (f) is also required and the application should be redesignated as a continuation-in-part. See M.P.E.P. 602.05

Response to Amendment

The declaration under 37 CFR 1.132 filed 06/23/2008 to overcome the rejection of claims 20, 21, 25 and 29–33 based upon Mitrani (U. S. Patent No. 5,753,612) has been considered. However, it is directed to a rejection that has been withdrawn because the claims have been amended to recite "up to about 5 ng of Activin per centimeter of said wound or fibrotic disorder" or "2.5 ng to up to about 5 ng of Activin per centimeter of said wound or fibrotic disorder" in the amendment filed 05/28/2008. Therefore, the sufficiency or insufficiency of this declaration to overcome the rejection of claims 20, 21, 25 and 29–33 prior to the amendment filed 05/28/2008 based upon Mitrani (U. S. Patent No. 5,753,612) is moot.

Response to Arguments

Applicant's arguments, see pages 6–13 of applicant's response, filed 05/28/2008, with respect to Mitrani (U. S. Patent No. 5,753,612) and De Krester (U. S. Patent No. 5,196,192) have been fully considered. However, they are directed to a rejection that has been withdrawn because the claims have been amended to recite "up to about 5 ng of Activin per centimeter of said wound or fibrotic disorder" or "2.5 ng to up to about 5 ng of Activin per centimeter of said wound or fibrotic disorder" in the amendment filed 05/28/2008. Therefore, the persuasiveness of these arguments is moot.

Conclusion

No claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (571) 272-0890. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 9:00 A.M. TO 5:30 P.M. IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, MANJUNATH RAO, CAN BE REACHED AT (571)272-0939.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE CENTRAL FAX NUMBER FOR OFFICIAL CORRESPONDENCE, WHICH IS (571) 273-8300.

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING MAY BE OBTAINED FROM THE PATENT APPLICATION INFORMATION RETRIEVAL (PAIR) SYSTEM. STATUS INFORMATION FOR PUBLISHED APPLICATIONS MAY BE OBTAINED FROM EITHER PRIVATE PAIR OR PUBLIC PAIR. STATUS INFORMATION FOR UNPUBLISHED APPLICATIONS IS AVAILABLE THROUGH PRIVATE PAIR ONLY. FOR MORE INFORMATION ABOUT THE PAIR SYSTEM, SEE HTTP://PAIR-DIRECT.USPTO.GOV. CONTACT THE ELECTRONIC BUSINESS CENTER (EBC) AT 866-217-9197 (TOLL-FREE) FOR QUESTIONS ON ACCESS TO THE PRIVATE PAIR SYSTEM,

/DAVID S ROMEO/
PRIMARY EXAMINER, ART UNIT 1647

DSR
SEPTEMBER 5, 2008